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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,110	12/02/2004	Shiroo Muraoka	61625 (70232)	1701
21874 7590 07/19/2007 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER VENC, DAVID J	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 07/19/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/501,110

Applicant(s)

MURAOKA ET AL.

Examiner

David J. Venci

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on September 13, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on July 8, 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 09/16/04; 08/14/06; 09/13/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Specification*

The abstract is objected to because the abstract does not disclose that which is new in the art to which the invention pertains. Since this patent application is in the nature of an improvement to old processes or compositions, the abstract should include the technical disclosure of the improvement. In addition, the abstract should not refer to purported merits or speculative applications of the invention.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, step (2), the phrase "immunogen denatured previously" lacks antecedent basis.

In claim 1, step (2), the phrase "the ionic surfactant used in step (1)" lacks antecedent basis.

In claim 1, step (2)(a), the phrase "the solution" lacks antecedent basis.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-7 and 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Knowles & Marchesi (4,658,022).

Knowles & Marchesi describe immunoassays (see Abstract, last sentence) comprising:

- (1) extracting/solubilizing a protein with an ionic surfactants (see e.g., col. 8, line 15, "sodium dodecylsulfate";
- (2) adding an antibody obtained by using the protein as immunogen (see col. 9, lines 56-60) to:
  - (a) the protein solution obtained in (1) without substantially diluting the solution (see lines 36-38, "A sufficient amount of the denatured protein must remain in solution or suspension in order to obtain useful immunobinding"; see *also*, sentence bridging cols. 8-9, "For guanidine[...] less than about 1.0 molar, with about 0.3 molar being particularly preferred") (paraphrasing mine).
- (3) detecting the antigen-antibody complex (see col. 10, lines 20-25).

With respect to claims 11, 12 and 17, Knowles & Marchesi describe assays for proteins found in buckwheat, wheat and peanuts (see col. 9, lines 16-20).

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3 and 8-10 are rejected under 35 U.S.C. 103(a) as obvious over Knowles & Marchesi (4,658,022) in view of Powell, CURRENT PROTOCOLS IN MOLECULAR BIOLOGY, Unit 17.14A, John Wiley & Sons, Inc. (1995).

Knowles & Marchesi describe immunoassays as substantially described *supra*.

Knowles & Marchesi do not specify particular sodium dodecyl sulfate (SDS) concentrations and 2-mercaptoethanol concentration in the "aqueous solvent" (*i.e.*, claims 2, 3 and 8). Knowles & Marchesi do not teach a boiling step (*i.e.*, claims 9 and 10).

However, Powell describes methods for preparing glycoproteins for characterization (see p. 17.14.1, first and second sentences), including fine procedural details. Specifically, Powell describes an "aqueous solvent" having at least 0.3% SDS and 1M 2-mercaptoethanol (see **BASIC PROTOCOL**, p. 17.14.2, *Materials*, "20% (w/v) sodium dodecyl sulfate (SDS)"; "1 M 2-mercaptoethanol (2-ME)"). In addition, Powell describes a boiling step lasting at least 5 minutes (see **BASIC PROTOCOL**, p. 17.14.3, *Digest with protease*, Step 7, "Boil 10 min").

It would have been obvious to a person of ordinary skill to optimize Knowles' & Marchesi's method using Powell's particular sodium dodecyl sulfate (SDS) concentrations, 2-mercaptoethanol concentration, and

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boiling step because Powell's steps remove "low-molecular-weight glycopeptides, degradation products, and sugar precursors", which Powell says is necessary prior to glycopeptide analysis (see *Critical Parameters and Troubleshooting*, p. 17.14.8., left column, item 1).

### **Conclusion**

No claims are allowable at this time.

Any inquiry concerning this communication should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



LONG V. LE 07/09/07

**SUPERVISORY PATENT EXAMINER  
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